

Applicant : Tommy Ekstrom
Serial No. : 09/367,950
Filed : August 18, 1999
Page : 2 of 7

Attorney's Docket No.: 06275-188001 / D 1576-1P US

In the Claims:

Please amend the claims as follows:

1-12. (Cancelled)

71 13. (Currently Amended) A method of prevention and treatment of an acute episode of asthma, which comprises

instructing a patient in need thereof to inhale an effective amount of a composition comprising, in admixture:

(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient which is budesonide;

characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient based on the patient's symptoms, as a treatment and a preventive measure, when the patient experiences an increase in asthma symptoms of an acute episode of asthma.

14. (Previously Amended) The method according to claim 13, wherein the molar ratio of (a) to (b) calculated as formoterol to budesonide is from 1:1 to 1:100.

15. (Previously Amended) The method according to claim 13, wherein the first active ingredient is formoterol fumarate dihydrate.

16. (Previously Amended) The method according claim 13, wherein the first active ingredient is the R,R enantiomer of formoterol.

17. (Previously Amended) The method according to claim 13, wherein a unit dose of formoterol lies in the range of from 1 µg to 48 µg, calculated as formoterol fumarate dihydrate.

18. (Previously Amended) The method according to claim 13, wherein the daily dose of formoterol, including maintenance therapy, lies in the range of from 1 µg to 100 µg, calculated as formoterol fumarate dihydrate.

Applicant : Tommy Ekstrom
Serial No. : 09/367,950
Filed : August 18, 1999
Page : 3 of 7

Attorney's Docket No.: 06275-188001 / D 1576-1P US

19. (Previously Amended) The method according to claim 13, wherein the second active ingredient is the 22R epimer of budesonide.

20. (Previously Amended) The method according to claim 13, wherein a unit dose of budesonide lies in the range of from 20 µg to 1600 µg.

21. (Previously Amended) The method according to claim 13, wherein the daily dose of budesonide, including maintenance therapy, lies in the range of from 20 µg to 4800 µg.

22. (Previously Amended) The method according to claim 13, wherein the particle size of the active ingredients (a) and (b) is less than 10 µm.

23. (Previously Amended) The method according to claim 13, wherein the composition additionally comprises one or more pharmaceutically acceptable additives, diluents or carriers.

24. (Original) The method according to claim 23, wherein the pharmaceutically acceptable additive, diluent or carrier is lactose monohydrate.

25. (Previously Added) The method according to claim 14, wherein the molar ratio of (a) to (b) calculated as formoterol to budesonide is from 1:1 to 1:70.

26. (Previously Added) The method according to claim 17, wherein a unit dose of formoterol lies in the range of from 3 µg to 12 µg, calculated as formoterol fumarate dihydrate.

27. (Previously Added) The method according to claim 18, wherein the daily dose of formoterol, including maintenance therapy, lies in the range of from 2 µg to 60 µg, calculated as formoterol fumarate dihydrate.

28. (Previously Added) The method according to claim 20, wherein a unit dose of budesonide lies in the range of from 50 µg to 400 µg.

29. (Previously Added) The method according to claim 21, wherein the daily dose of budesonide, including maintenance therapy, lies in the range of from 30 µg to 3200 µg.

Applicant : Tommy Ekstrom
Serial No. : 09/367,950
Filed : August 18, 1999
Page : 4 of 7

Attorney's Docket No.: 06275-188001 / D 1576-1P US

18
30. (Previously Added) The method according to claim 15 further comprising instructing the patient to inhale the composition as a rescue medication.

19
31. (Previously Added) The method according to claim 15 further comprising instructing the patient to take a second composition, comprising a glucocorticosteroid, on a regular basis as a maintenance treatment.

20
32. (Previously added) The method according to claim 15 further comprising instructing the patient to use the composition as a complement to maintenance treatment of the patient's asthma.

71
ant
21
33. (Currently amended) The method according to claim 15 further comprising instructing the patient to inhale an effective amount of the composition as a preventive measure prior to encountering an event that triggers an acute episode of asthma triggering event.

22
24. (Currently amended) The method of claim 33 wherein the event triggering the acute episode of asthma triggering event is selected from the group consisting of exposure to cold air, exercise, and exposure to a smoky environment.

23
35. (Currently amended) A method of prevention and treatment of an acute episode of asthma, which comprises

instructing a patient in need of prevention or treatment of an acute episode of asthma to inhale an effective amount of a composition comprising, in admixture:

(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient which is budesonide;

characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient based on the patient's symptoms, as a complement to maintenance treatment of the patient's asthma.

F

Applicant : Tommy Ekstrom
Serial No. : 09/367,950
Filed : August 18, 1999
Page : 5 of 7

Attorney's Docket No.: 06275-188001 / D 1576-1P US

24
36. (Currently amended) A method of prevention and treatment of an acute episode of asthma, which comprises

instructing a patient in need thereof to inhale an effective amount of a composition comprising, in admixture:

(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient which is budesonide;

7H
Cmt
characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient, when the patient is expecting to encounter a trigger of an acute episode of asthma trigger, as a preventative measure.

37. (Cancelled)

25
38. (Currently amended) The method of claim 13 further comprising instructing the patient to use the composition as a complement to maintenance treatment of the patient's acute episodes of asthma.

39. (Cancelled)

40. (Cancelled)

41. (Cancelled)

26
42. (Currently amended) A method of prevention and treatment of an acute episode of asthma, which comprises

instructing a patient in need thereof to inhale an effective amount of a composition comprising, in admixture:

(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and


(b) a second active ingredient which is budesonide;

3

Applicant : Tommy Ekstrom
Serial No. : 09/367,950
Filed : August 18, 1999
Page : 6 of 7

Attorney's Docket No.: 06275-188001 / D 1576-1P US

characterized in that the patient is instructed to take a maintenance dose of the composition, and, if the patient experiences ~~asthma-symptoms~~ of an acute episode of asthma, to inhale additional doses as needed to improve control and provide acute relief.



3